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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/862,710   | 05/23/2001  | Chirag B. Shah       | P296 DIV1           | 1806             |
| 28390  | 7590        | 10/16/2003           | EXAMINER            |                  |
| MEDTRONIC AVE, INC.<br>3576 UNOCAL PLACE<br>SANTA ROSA, CA 95403 |             |                      | ROBERTSON, JEFFREY  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |

1712

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                    |  |
|------------------------------|---|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/862,710    | <b>Applicant(s)</b><br>SHAH ET AL. |  |
|                              | <b>Examiner</b><br>Jeffrey B. Robertson | <b>Art Unit</b><br>1712            |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-13 and 60-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-13 and 60-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 4-13, and 60-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For claims 1 and 60, applicant has amended the claims to include the limitation "provided that said biopolymer is not a nucleic acid". The examine is unable to find support for this limitation in the specification. The specification fails to positively recite nucleic acid biopolymers, and also the biopolymer is described in terms of heparin biopolymers. See M.P.E.P §2173.05(i), the relevant portion of which is reproduced below:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4-13, and 60-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claims 1, 4-13, and 60-78, applicant sets forth "[a] coating composition" in the first line of the claims. However, applicant then sets forth the limitation that the product is coated onto a surface of a substrate. This creates confusion as to what applicant is claiming. Is applicant claiming a composition or a coated surface?

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 7, 12, 60, 64, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Billmers (U.S. Patent No. 4,973,680).

For claims 17, 60, and 64, in column 6, lines 33-66, Billmers teaches that a silane, glycidylxypropyltrimethoxysilane, is reacted with a polysaccharide (biopolymer) containing a hydroxyl group to form a covalently bonded product. In Example 1,

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columns 12-13, Billmers teaches the synthesis of a silane biopolymer adduct. For claims 1 and 60, in column 7, lines 15-33, Billmers teaches that this material is coated on glass where the silanol group of the hydrolyzed silane reacts with the glass. Billmers does not teach the use of a primer.

For claims 12 and 69, in column 11, lines 58-68, Billmers teaches an additive in the form of a surface-active agent (emulsifier).

7. Claims 1 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley et al. (U.S. Patent No. 6,048,695).

For claims 1 and 60, in column 5, line 55 through column 6, line 47, Bradley teaches that an epoxy-containing silane is reacted with a biopolymer (DNA) and that subsequently this product is affixed to an underivatized glass surface. Bradley does not teach any other components added to this product in the Example.

### ***Response to Arguments***

8. Applicant's arguments filed 8/01/03 have been fully considered regarding the Bradley reference, but they are not persuasive. As set forth above, the negative limitation added to claims 1 and 60 is not considered by the examiner to be supported by the specification, and as a consequence the rejection of claims 1 and 60 has been continued. For the Nagata reference, the rejection has been withdrawn in light of applicant's amendments to the claims.

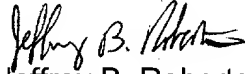
### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey B. Robertson whose telephone number is (703) 306-5929. The examiner can normally be reached on Mon-Fri 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Jeffrey B. Robertson  
Primary Examiner  
Art Unit 1712

JBR  
October 9, 2003